

Food and Drug Administration, HHS

§ 862.1400

acid cystine) in urine. The identification of urinary homocystine is used in the diagnosis and treatment of homocystinuria (homosystine in urine), a heritable metabolic disorder which may cause mental retardation.

(b) *Classification*. Class II.

§ 862.1380 Hydroxybutyric dehydrogenase test system.

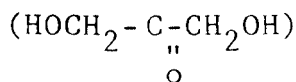
(a) *Identification*. A hydroxybutyric dehydrogenase test system is a device intended to measure the activity of the enzyme alpha-hydroxybutyric dehydrogenase (HBD) in plasma or serum. HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38787, July 25, 2001]

§ 862.1385 17-Hydroxycorticosteroids (17-ketogenic steroids) test system.

(a) *Identification*. A 17-hydroxycorticosteroids (17-ketogenic steroids) test system is a device intended to measure corticosteroids that possess a dihydroxyacetone



moiety on the steroid nucleus in urine. Corticosteroids with this chemical configuration include cortisol, cortisone 11-desoxycortisol, desoxycorticosterone, and their tetrahydroderivatives. This group of hormones is synthesized by the adrenal gland. Measurements of 17-hydroxycorticosteroids (17-ketogenic steroids) are used in the diagnosis and treatment of various diseases of the adrenal or pituitary glands and gonadal disorders.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May. 1, 1987; 52 FR 29468, Aug. 7, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1390 5-Hydroxyindole acetic acid/serotonin test system.

(a) *Identification*. A 5-hydroxyindole acetic acid/serotonin test system is a device intended to measure 5-hydroxyindole acetic acid/serotonin in urine. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1395 17-Hydroxyprogesterone test system.

(a) *Identification*. A 17-hydroxyprogesterone test system is a device intended to measure 17-hydroxyprogesterone (a steroid) in plasma and serum. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1400 Hydroxyproline test system.

(a) *Identification*. A hydroxyproline test system is a device intended to measure the amino acid hydroxyproline in urine. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone disease such as Paget's disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

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subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1405 Immunoreactive insulin test system.

(a) *Identification.* An immunoreactive insulin test system is a device intended to measure immunoreactive insulin in serum and plasma. Immunoreactive insulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus, and hypoglycemia.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1410 Iron (non-heme) test system.

(a) *Identification.* An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

(b) *Classification.* Class I.

§ 862.1415 Iron-binding capacity test system.

(a) *Identification.* An iron-binding capacity test system is a device intended to measure iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

(b) *Classification.* Class I.

§ 862.1420 Isocitric dehydrogenase test system.

(a) *Identification.* An isocitric dehydrogenase test system is a device intended to measure the activity of the enzyme isocitric dehydrogenase in serum and plasma. Isocitric dehydrogenase measurements are used in the

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diagnosis and treatment of liver disease such as viral hepatitis, cirrhosis, or acute inflammation of the biliary tract; pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply to the lungs), and diseases associated with pregnancy.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

§ 862.1430 17-Ketosteroids test system.

(a) *Identification.* A 17-ketosteroids test system is a device intended to measure 17-ketosteroids in urine. Measurements of 17-ketosteroids are used in the diagnosis and treatment of disorders of the adrenal cortex and gonads and of other endocrine disorders, including hypertension, diabetes, and hypothyroidism.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2307, Jan. 14, 2000]

§ 862.1435 Ketones (nonquantitative) test system.

(a) *Identification.* A ketones (nonquantitative) test system is a device intended to identify ketones in urine and other body fluids. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2307, Jan. 14, 2000]